THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: O'Brien et al.

FILED: August 29, 2003

SERIAL NO.: 10/652,846

FOR: Extracellular Serine Protease

ART UNIT: *<u>aaaaaaaaaaa</u>* 1644

EXAMINER:

Huynh, P.N.

DOCKET:

D6020CIP4

Mail Stop Appeal Brief - Patents **Commissioner of Patents** P.O. Box 1450 Alexandria, VA 22313

ATTENTION: Board of Patent Appeals and Interferences

RESPONSE TO NOTICE OF NON-COMPLIANT APPEAL BRIEF

Dear Sir:

In response to the Notice of Non-Compliant Appeal Brief mailed on December 23, 2008, the Applicants submit an Amended Appeal Brief herewith. Please consider the following remarks. Reconsideration of the Appeal Brief is requested.

Respectfully submitted,

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REMARKS

The Appeal Brief submitted on November 24, 2008 was found defective for lack of a statement of the status of all claims. The Status of Claims section has been amended to include a statement regarding the status of claims 56-66. The Applicants believe that the Amended Appeal Brief is compliant.

The Applicants believe that no fees are outstanding in the above-referenced application. However, if this is in error, please debit any additional fees due from Deposit Account No. 07-1185 on which Applicant's counsel is allowed to draw.

Respectfully submitted,

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ATTENTION: Board of Patent Appeals and Interferences

AMENDED APPEAL BRIEF

Dear Sir:

This Amended Appeal Brief submitted herewith corrects the defects of the Appeal Brief submitted on November 21, 2008. The fees required under 37 C.F.R. §41.20(b)(2) and other applicable fees were submitted with the original Appeal Brief. The Applicants believe that no fees are outstanding in the abovereferenced application. However, if this is in error, please debit any additional fees due from Deposit Account No. 07-1185 on which Applicant's counsel is allowed to draw.

Respectfully submitted,

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I. REAL PARTY IN INTEREST

The real party in interest is The University of Arkansas for Medical Sciences.

II. RELATED APPEALS AND INTERFERENCES

Appellant is aware of no related appeals and interferences of the present invention.

III. STATUS OF CLAIMS

Originally, claims 1-66 were filed and being prosecuted in this Application. The withdrawn claims 1-51 and 56-66 were canceled. Of the pending claims 52-55, claim 52 is independent and the subject of this appeal.

IV. STATUS OF AMENDMENTS

Claims 52 and 55 were amended in response to a Restriction Requirement, submitted October 6, 2006. In response to an Office Action, submitted November 5, 2006, claims 52 and 54 were amended. A Notice of Appeal was filed July 22, 2008 appealing the rejection of the pending claims 52-55, as shown in Appendix A.

V. <u>SUMMARY OF CLAIMED SUBJECT MATTER</u>

The subject matter of independent claim 52 is drawn to an isolated DNA encoding a TADG-14 protein variant. The DNA is identified as the sequence of SEQ ID NO: 6 plus the inclusion of an intron sequence between exon 2 and exon 3 of SEQ ID NO: 6 (pg 3, lines 16-18; pg 54, lines 12-14). This DNA may be incorporated into a vector which comprises regulatory elements and is adapted for expression in a cell (pg 21, lines 7-14). This vector may then be transfected into a host bacterial, mammalian, plant or insect cell (pg 21, lines 15-21).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claim 52 is anticipated by **Mitsui** et al., Eur J Biochem 260: 627-634, 1999) under 35 U.S.C. §102(b).

VII. ARGUMENT

Rejection of claim 52 under 35 U.S.C. §102(b) over over Mitsui et al.

It is well established that in order to anticipate a claim under 35 U.S.C. §102(b), each and every element of the claim should be described in a single prior art reference, either expressly or inherently. Importantly, the identical invention must be shown in as complete detail as is contained in the instant invention. Applicant's claim 52 is directed towards an isolated DNA sequence that differs from the nucleic acid sequence of SEQ ID NO: 6 due to the inclusion of an intron sequence between exon 2 and exon 3 of SEQ ID NO: 6 which encodes the TADG-14 protein variant with the sequence shown in SEQ ID NO: 75.

Applicants respectfully submit that **Mitsui** *et al.* do not teach the DNA sequence that differs from SEQ ID NO:6 due to the inclusion of an intron sequence between exon 2 and exon 3 as recited in Applicants' claim 52. **Mitsui** *et al.* do not teach the same vector comprising the regulatory elements necessary for expressing the reference DNA in host cell. Applicants recite an isolated DNA that differs from the nucleic acid sequence of SEQ ID NO: 6 due to the inclusion of an intron sequence between exon 2 and exon 3 of SEQ ID NO: 6. Such a DNA encodes a TADG-14 protein variant that has an amino acid sequence of SEQ ID NO: 75. Thus, the instant claim is drawn to a DNA sequence that encodes a protein of SEQ ID NO: 75 and not drawn to the protein of SEQ ID NO: 75. Moreover, the instant specification discloses that there are

differences between TADG-14 and neuropsin differ at the nucleotide level (pg. 48, lines 6-14). The TADG-14 mRNA has an additional 491 bases of 5' UTR that were not found in human neuropsin. Also, the nucleotides preceding the poly (A) tail in the 3' UTR are not homologous.

In distinct contrast, **Mitsui** et al. disclose a difference nucleotide sequence which encodes amino acid sequences of neuropsin.

Second, although **Mitsui** *et al.* teach insertion of exon 2 and exon 3 in the nucleotide sequence of neuropsin (Figure 4A), this nucleotide sequence of neuropsin is not the same as SEQ ID NO: 6. Accordingly, **Mitsui** *et al.* do not teach the same vector as the instant invention since the TADG-14 and neuropsin differ at the nucleotide level.

For these reasons, Applicants submit that claim 52 is not anticipated under 35 U.S.C. §102(b) by **Mitsui** *et al.*. Accordingly, Applicants respectfully request the Board of Patent Appeals and Interferences to reverse the rejection of claim 52-55 under 35 U.S.C. §102(b).

Date: (

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Respectfully submitted,

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VIII. CLAIMS APPENDIX

Claim 52. An isolated DNA that differs from nucleic acid sequence of SEQ ID NO: 6 due to inclusion of an intron sequence between exon 2 and exon 3 of SEQ ID NO: 6, said DNA encoding a TADG-14 protein variant with an amino acid sequence shown in SEQ ID NO: 75.

Claim 53. A vector capable of expressing the DNA of claim 52, wherein said vector is adapted for expression in a cell and comprises regulatory elements necessary for expressing said DNA in said cell.

Claim 54. A host cell transfected with the vector of claim 53, wherein said vector expresses a TADG-14 protein variant with the amino acid sequence shown in SEQ ID NO. 75.

Claim 55. The host cell of claim 54, wherein said cell is a bacterial cell, a mammalian cell, a plant cell or an insect cell.

IX. EVIDENCE APPENDIX

None

X. RELATED PROCEEDINGS APPENDIX

None

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CERTIFICATE OF MAILING UNDER 37 §C.F.R. 1.8

Dear Sir:

I hereby certify under 37 CFR 1.8 that the following correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to MS Appeal Brief, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

- 1) Response to Notice of Non-Compliant Appeal Brief (2 pgs)
- 2) Amended Appeal Brief (13 pgs)

Please return the enclosed postcard acknowledging receipt of this correspondence.

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